## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE In re Patent Application of Atty ARC-4865-62 Dkt. roos ro dua C# M# CAVAZZA C/A.U. 1617 Serial No. 10/667,482 Examiner: Kim September 23, 2003 Date: August 6, 2007 Filed: COMPOSITION FOR THE PREVENTION AND TREATEMENT OF KIDNEY Title: DYSFUNCTIONS AND DISEASES Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir: RESPONSE/AMENDMENT/LETTER This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon. ☐ Correspondence Address Indication Form Attached. Fees are attached as calculated below: Total effective claims after amendment 27 minus highest number previously paid for 27 (at least 20) = x \$50.00 \$0.00 (1202)/\$0.00 (2202) \$ Independent claims after amendment 17 minus highest number previously paid for (at least 3) =x \$200.00 \$0.00 (1201)/\$0.00 (2201) \$ 17 If proper multiple dependent claims now added for first time, (ignore improper); add \$360.00 (1203)/\$180.00 (2203) \$ Petition is hereby made to extend the current due date so as to cover the filing date of this One Month Extension \$120.00 (1251)/\$60.00 (2251) paper and attachment(s) Two Month Extensions \$450.00 (1252)/\$225.00 (2252) Three Month Extensions \$1020.00 (1253/\$510.00 (2253) Four Month Extensions \$1590.00 (1254/\$795.00 (2254) Five Month Extensions \$2160.00 (1255/\$1080.00 (2255) \$ \$130.00 (1814)/\$65.00 (2814) \$ Terminal disclaimer enclosed, add Applicant claims "small entity" status. Statement filed herewith Rule 56 Information Disclosure Statement Filing Fee \$180.00 (1806) \$ 0.00 Assignment Recording Fee \$40.00 (8021) \$ 0.00 \$ 0.00 Other: **TOTAL FEE \$** 0.00 CREDIT CARD PAYMENT FORM ATTACHED. The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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By Atty: Arthur R. Crawford Reg. No. 25,327

Signature:



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

CAVAZZA Atty. Ref.: 4865-62; Confirmation No. 9079

Appl. No. 10/667,482 TC/A.U. 1617

Filed: September 23, 2003 Examiner: Kim

For: COMPOSITION FOR THE PREVENTION AND TREATEMENT OF KIDNEY

DYSFUNCTIONS AND DISEASES

\* \* \* \* \* \* \* \* \* \* \*

August 7, 2007

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## **RESPONSE**

This is responsive to the Official Action of July 17, 2007 and the requirement for election of species presented in it. Claims 9-35 are pending in the application.

From among the five different species identified on page 2 of the Official Action, applicants select **lithium** as the elected specie. Claims 9-16, 23, 24, 31 and 32 "read on" the elected specie.

It is counsel's understanding that this request for and identification of a single species is primarily for convenience and thoroughness of searching in order to outline an initial search area and then expand it, as appropriate, to include all five of the various identified species.

Nevertheless, applicants traverse the election requirement.

Firstly, the specification of the invention contains all necessary elements to define a unitary invention.

On page 1, first paragraph, the object of the invention is specifically and clearly stated. The invention provides <u>one single</u> solution to the <u>specific and single</u> technical problem of

prevention and treatment of <u>kidney</u> dysfunctions and diseases. The skilled person to whom the present specification is directed to is a medical practitioner and an expert in nephrology. So, we have <u>one</u> of each: technical problem, technical solution, technical field and expert in the field.

In the third paragraph, the concept is repeated: "nephropathy", <u>independently from its origin</u>. Therefore, it is evident even here that the invention responds to <u>one</u> single concept.

The skilled person will understand that the present invention provides <u>one single</u> solution for treating nephropathy, independently from its origin. *See* also page 2, paragraph 3.

The various species (5) identified by the Examiner (lithium, antibiotics, anticancer agents, mycotoxin, ochratoxin A) have different chemical origins, but all of them have the same technical feature in the frame of the present invention, namely all of them cause (or are believed to cause) nephrotoxicity.

In the pending Office Action, the Examiner did not point out any technical reason showing that the invention is not unitary. In other words, the Examiner did not show how the presently claimed invention does not comply with the requirements of Rule 13.1 PCT.

Applicant respectfully directs attention to PCT Rule 13.2:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in <u>Rule 13.1</u> shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The technical relationship is represented by nephropathy, even though from different origins, but represented by a single pathology focusing on a single organ, and is treated by a single technical expert. The "special technical feature" is represented by the special combination of acetyl L-carnitine and propionyl L-carnitine. This special technical feature represents a contribution over the prior art, as discussed in the specification of the invention and in applicant's remarks already of record.

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Applicant also respectfully recalls the provisions of PCT Rules 13.2 and 13.3:

13.3 Determination of Unity of Invention Not Affected by Manner of Claiming

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

## 13.4 Dependent Claims

Subject to <u>Rule 13.1</u>, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention.

In view of the above arguments, withdrawal of the election of species and examination of the application in the basis of pending claims 9-35 is respectfully requested.

Respectfully submitted,

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